

**UNITED STATES DISTRICT COURT FOR THE
DISTRICT OF VERMONT**

ETHEL KELLOGG,

Plaintiff,

v.

WYETH, Individually and as Successor-in-
Interest to A.H. ROBINS COMPANY, INC.
and AMERICAN HOME PRODUCTS
CORPORATION; SCHWARZ PHARMA,
INC.; ACTAVIS, INC.; ACTAVIS-
ELIZABETH, L.L.C.; ALPHARMA, INC.;
PUREPAC PHARMACEUTICAL
COMPANY, INC.; TEVA
PHARMACEUTICALS, USA, INC.; BARR
PHARMACEUTICALS, INC.; PLIVA, INC.;
and DRUG COMPANY DOES 1
THROUGH 10, inclusive,

Defendants.

HONORABLE WILLIAM SESSIONS, III

DOCKET NO. 2:07-CV-00082

**ACTAVIS’S MOTION FOR STAY
OF ALL PROCEEDINGS**

Defendants Actavis, Inc. and Actavis-Elizabeth, LLC (collectively, “Actavis”), by and through counsel, request that this Court stay all proceedings with regard to the above-captioned case until the United States Supreme Court has ruled on the generic preemption issues raised in *Demahy v. Actavis, Inc.*, 593 F.3d 428 (5th Cir. 2010), *certiorari granted* No. 09-1501 (letter from Office of the Clerk, Supreme Court of the United States, attached as Exhibit 1), and *Mensing v. Wyeth, Inc.*, 588 F.3d 603 (8th Cir. 2009), *certiorari granted* Nos. 09-993 and 09-1039 (letter from Office of the Clerk, Supreme Court of the United States, attached as Exhibit 2).

Defendants raised these very issues—whether a plaintiff’s personal injury claims based on a failure-to-warn theory are preempted by the Food Drug and Cosmetic Act—in a motion to

dismiss (Doc. 211), which this Court denied (Doc. 267). The Supreme Court will hear argument in March, with a decision expected by July.

I. The Supreme Court's holding may be outcome determinative.

The issues raised in the *Demahy* and *Mensing* appeals may be outcome-determinative and end, or at least fundamentally restructure, this litigation. If the Court rules in favor of the generic manufacturers of metoclopramide, reversing either appellate court, it will mean that Plaintiff's failure-to-warn claims are preempted and may not proceed. This outcome would require the dismissal of Plaintiff's claims against generic manufacturers and would necessitate that this Court reevaluate Plaintiff's claims to determine which, if any, could proceed against any remaining defendants.¹ Consequently, further proceedings at this time would occur in a fog of uncertainty created by the Supreme Court's pending decision and run the risk of wasting the resources of this Court and the parties in the event that the Supreme Court holds that these failure-to-warn actions are preempted.

II. Even if this case proceeds, the Supreme Court's holding will guide the remainder of this litigation.

Even if the Supreme Court does not hold these failure-to-warn claims preempted, its ruling may narrow the sorts of claims that a failure-to-warn plaintiff may press against a generic manufacturer. For example, the Court could embrace the view of the Food and Drug Administration, which has taken the position in an amicus brief filed by the United States Solicitor General (U.S. Brief, attached as Exhibit 3) that federal law precludes a claim that

¹ Plaintiff alleges claims against Wyeth, Inc. based on the promotion of metoclopramide, but not on any exposure to Wyeth's branded product. The Supreme Court is not expected to address this issue, but dismissal of the claims against generic manufacturers would nevertheless affect Wyeth by narrowing the scope of litigation and refocusing the remaining discovery and briefing on different issues.

generic manufacturers may unilaterally revise product labeling or unilaterally provide different warnings to physicians:²

- A generic manufacturer cannot unilaterally change its approved labeling under the “Changes Being Effected” process described in 21 C.F.R. § 314.70(c). (U.S. Brief at 13).
- A generic manufacturer cannot change its approved labeling to add or strengthen a warning through use of the “Prior Approval Supplement” process in 21 C.F.R. § 314.70(b)(3). (U.S. Brief at 14-15).
- A generic manufacturer cannot unilaterally send “Dear Healthcare Provider” letters to physicians advising about additional risk information. Correspondence of this sort “would likely be misleading.” (*Id.* at 17-18).

In short, the FDA embraced the core of Defendants’ position in this litigation—that a generic product’s labeling “must be the same as the listed [brand-name] drug product’s labeling because the listed drug product is the basis for ANDA approval.” (*Id.* at 14 (citing 57 Fed. Reg. at 17,961)).

It is now for the Supreme Court to identify which claims, if any, a plaintiff may advance in a failure-to-warn action against a generic drug manufacturer. The Court’s ruling may profoundly affect this action by clarifying which issues a jury may appropriately consider and by controlling the manner in which this Court will instruct jurors on the applicable law. For this reason, a stay will save this Court and the parties substantial time and resources by ensuring that these cases do not proceed based on theories that the Supreme Court may subsequently hold to be not viable. If the Supreme Court rules in such a way that allows those claims to proceed, the parties and this Court will then be able to proceed with the benefit of the Supreme Court’s

² The Supreme Court chose to grant certiorari despite the Solicitor General’s recommendation that the Court should deny certiorari because federal law does not “categorically” preempt failure-to-warn claims. The Court’s decision to grant certiorari is also exceptional under the circumstances here, where a split of authority among the Circuit Courts of Appeal has not yet emerged.

guidance. And because a ruling is expected by July 2011, the delay in this case will be relatively minor and the parties will be able promptly to resume the litigation, if any remains.

III. A stay will prevent the parties and this Court from wasting resources and incurring unnecessary expenses.

Given the chance that the Supreme Court's opinion will end much of this litigation, further proceedings at this time would risk wasting the time and money of both parties. A substantial amount of discovery remains as of this time, including the depositions of expert witnesses. (*See* Joint Motion to Amend Scheduling Order, Doc. 268). A Supreme Court ruling in the Defendants' favor will eliminate the need for much of that discovery, saving the parties tens of thousands of dollars. It will also eliminate the need for this Court to consider potentially unnecessary motions regarding experts and evidentiary issues that would become moot if the Supreme Court were to hold that failure-to-warn claims against the generic Defendants are preempted. And most importantly, it will prevent this Court from having to prepare this case, currently scheduled to be trial-ready by May 2, 2011, for a lengthy trial that may prove unnecessary after the Supreme Court's decision.

This Court's power to stay proceedings "is incidental to the power inherent in every court to control the disposition of the causes on its docket with economy of time and effort for itself, for counsel, and for litigants." *Landis v. North Am. Co.*, 299 U.S. 248, 254 (1936). In deciding whether to exercise that discretion, this Court should consider "the potentiality of [this case] having a dispositive effect on the case to be stayed, the judicial economy to be saved by waiting on a dispositive decision, the public welfare, and the hardship/prejudice to the party opposing the stay, given its duration." *Michael v. Ghee*, 325 F. Supp.2d 829, 831 (N.D. Ohio 2004). Here, the fact that the Supreme Court's decision "may have a dispositive effect on the instant case . . .

weighs heavily in favor of granting the stay.” *Id.* (staying litigation because the Supreme Court granted certiorari on a potentially dispositive issue). A stay is particularly well-advised where, as here, a “case is massive and complex” and “[t]he Supreme Court’s answer to the question of law before it could negate the need . . . to delve into the vast majority of the legal issues presented” *Id.* at 832-33. As the *Michael* Court recognized, “[i]t makes little sense to undertake the herculean task of plodding through the motions when one decision by the Supreme Court could invalidate the entire case. This factor weighs heavily in favor of a stay.” *Id.*³

CONCLUSION

Plaintiff, Defendants, and this Court alike will benefit from a stay of all proceedings by saving enormous amounts of time and resources that could prove wasted if the Supreme Court holds that failure-to-warn claims like the one Plaintiff asserts are preempted. Those potential savings dwarf the inconvenience of delaying further proceedings until the Supreme Court issues its ruling, which is expected by July 2011. For these reasons, Actavis respectfully requests that this Court stay all activity in this case until such time as the Supreme Court has issued its ruling.

³ Other courts have stayed virtually identical litigation against the generic manufacturers of metoclopramide pending the decision of the Supreme Court. *See e.g. Theresa Huck v. PLIVA, Inc.*, No. LACV01894 (Iowa Dist. Ct. Dec. 15, 2010) (staying trial date and pre-trial deadlines);

Dated: January 4, 2011

/s/ Stephen J. Soule

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CERTIFICATE OF SERVICE

I, Stephen Soule, Esq., hereby certify that a true and correct copy of the *Defendants'*

Motion for Stay of All Proceedings was served on the following individuals through the CM/ECF

system on January 4, 2011:

For Plaintiff Ethel Kellogg

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Jeffrey R. Pilkington and Philip Butler

For Defendants Wyeth

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